K021780

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General Electric Medical Systems

Attachment 3 pg 1 of 4

Advantage Sim 6.0
510 (k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Identification of submitter:**

Larry A. Kroger. Ph.D.
Senior Regulatory Program Manager
3000 N. Grandview Blvd
Waukesha, 53188
USA
Telephone: 262-544-3894
Fax: 262-544-3863
Date Prepared: February 26, 2002

2. **Identification of Product:**

Device name	Advantage Sim 6.0.
Classification name	Radiation therapy simulation system per 21CFR Section 892 5840
Manufacturer/ Distributor	General Electric Medical Systems 283, Rue de la Minière 78533 BUC Cedex France

3. **Marketed Devices**

Advantage Sim 6.0 is substantially equivalent to the device listed below:

Model:	Advantage Sim 1.2
Manufacturer:	General Electric Medical Systems
510 (k):	K951830

4. **Device Description :**

Advantage Sim 6.0. is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning.
Anatomical volumes can be defined in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. The

geometric parameters of a proposed treatment field are selected to allow non-dosimetric, interactive optimization of field coverage.
Defined anatomical structures and geometric treatments fields are displayed on transverse CT images, on reformatted sagittal, coronal or oblique images, on 3 D views created from the CT images, or on a beam eye's view display of defined structures with or without the display of defined structures with or without the display of digittaly reconstructed radiograph.

The GE Advantage Sim 6.0 has to ensure relations with the following external systems:

Data Export

Image, volume and plan data are exported in accordance with DICOM V3.0.
Implementation profile is available on request. NOTE: Any treatment planning system connected to Advantage Sim 6.0. must be DICOM 3.0 compatible and capable of reading DICOM RT Plan and RT Structure Set.
Export of treatment plan data to any external system, and its correct interpretation by that system, must be fully validated before use.
Advantage Sim 6.0 stores isocenter coordinates and user defined marker coordinates onto an external accessible directory using a published protocol readable by external mobile laser controller.

RT Data Import

Image, volume and plan data can be imported in accordance with the RT objects of the DICOM Standard. Import of treatment plan data from an external system, and its correct interpretation by Advantage Sim 6.0, must be validated before use.

Hardcopy

Hardcopy of all displays and plan data can be made at selected magnification on paper or transparency material. Users can print DRR to film at user defined SID if equipped with an Advantage Workstation 6.0. compatible Laser camera** (** Laser camera must be adequate for scaled printing), with the appropriate AW Laser Camera Interface. (AW Option).
Hardcopy of beam parameters and of isocenter coordinates, using IEC standard, can be made on an optional Postscript printer

Archiving

Advantage Sim 6.0 can save DICOM images and DICOM RT objects on single-session DICOM CD R using an optional CD ROM writer.

Configuration Requirements

Advantage Sim 6.0 can be installed only on validated Advantage Workstation with single or dual color monitor.

The GE Advantage Sim 6.0 is designed and produced by GE Medical Systems and has been previously submitted to PMN (K951830).

5. Indications for Use

Advantage Sim 6.0 is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning.
Anatomical volumes can be defined in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. The geometric parameters of a proposed treatment field are selected to allow non-dosimetric, interactive optimization of field coverage.
Defined anatomical structures and geometric treatments fields are displayed on transverse CT images, on reformatted sagittal, coronal or oblique images, on 3 D views created from the CT images, or on a beam eye's view display with or without the display of defined structures with or without the display of digittaly reconstructed radiograph.

6. Comparison with Predicate Device

The GE Advantage Sim 6.0 is substantially equivalent to the following device:

Advantage Sim 1.2
Manufacturer: GE Medical Systems
510(k): K951830

Both of Advantage Sim 6.0 and Advantage Sim 1.2 provides complete volume definition and geometric beam placement capability for radiotherapy. It is then able to compute a DRR for any type of patient set-up and fully replaces a classic simulator

7. Conclusions

The entire potential new hazards has been studied and controlled by a Risk Management Plan:

- A hazard analysis/ Risk Management Summary

- A software development and validation process
- A software verification plan

Advantage Sim 6.0 provides images comparable to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

General Electric Medical Systems
% Mr. Wolfram Gmelin
Technical Manager
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K021780
Trade/Device Name: Advantage SIM 6.0
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: 90 KPQ
Dated: July 15, 2002
Received: July 16, 2002

Dear Mr. Gmelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1

General Electric Medical Systems

STATEMENT OF INTENDED USE

Device name: Advantage Sim 6.0

Indication For Use:

Advantage Sim 6.0 is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning.
Anatomical volumes can be defined in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. The geometric parameters of a proposed treatment field are selected to allow non-dosimetric, interactive optimization of field coverage.
Defined anatomical structures and geometric treatments fields are displayed on transverse CT images, on reformatted sagittal, coronal or oblique images, on 3 D views created from the CT images, or on a beam eye's view display with or without the display of defined structures with or without the display of digittaly reconstructed radiograph.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021780

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